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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,997	04/24/2000	Ganesh Venkataraman	M0656/7055 (HCL)	7686
23628	7590	04/30/2004	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

## Office Action Summary

### Application No.

09/557,997

### Applicant(s)

VENKATARAMAN ET AL.

### Examiner

Carolyn L Smith

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36,37 and 54-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36,37 and 54-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3152004</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's amendments and remarks, filed 3/8/04, are acknowledged. Cancelled claims 1-35 and 38-53 and new claims 54-72 are acknowledged.

Applicant's arguments, filed 3/8/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The information disclosure statement, filed 3/15/04, has been fully considered.

Claims 36-37 and 54-72 are herein under examination.

#### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a system and method for analyzing sequences of chemical units, whereas in contrast the elected claims are specifically directed to a only a method for analyzing sequences of chemical units.

This objection is maintained.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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The rejection of claims 36 and 37 is maintained and newly applied to new claims 54-72 under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to lack any physical result performed outside of a computer.

This rejection is maintained (claims 36-37), necessitated by amendment (new claims 54-72), and reiterated for reasons of record.

As stated in MPEP § 2106, (IV)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(2)(b)(i)), or (B) be limited to a practical application within the technological arts (discussed in MPEP § 2106 (IV)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(2)(b)(i), the independent physical acts may be post- or pre-computer processing activity as described below:

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical

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objects or activities. Schrader, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval Arrhythmia, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; Abele, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See Arrhythmia, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 36-37 and 54-72 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

The rejection of claims 36 and 37 is maintained and newly applied to new claims 54-72 under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

This rejection is maintained (claims 36-37), necessitated by amendment (new claims 54-72), and reiterated for reasons of record.

As stated in MPEP § 2106, (IV)(B)(1), if the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59.

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Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Claims 36-37 and 54-72 do not fulfill any of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Applicants state that claims 36 and 37 are directed to a practical application (MPEP § 2106 IV.B.2.b.ii). This is found unpersuasive a practical application does not appear to be accomplished in these claims. Regarding practical application, the MPEP § 2106

(IV)(B)(2)(b)(ii) states the following example:

A computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

Comparing the above scenario to claims 36 and 37, the claimed method that merely determines whether the complete building blocks of a query sequence match those of a polysaccharide are comparable to the nonstatutory example given above as it does not appear to have a valid practical application applied to the match determination. The claimed invention falls more into the example of noise analysis. In this example, it is not until the noise is filtered that a practical application is clearly expressed. In the instant invention, clarification in the

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claims of what practical application the sequence match analysis provides would nullify this rejection. This issue is newly applied to new claims 54-72 due to their dependency from claim 36.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63, 65-68, and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants point to pages 2 and 3 of the specification as well as the originally filed claims for support of new claims 54-72. While support is seen for new claims 54-62, 64, and 71, written support appears to be lacking for “exact chemical structure” (claim 63), “molecular weight” (claim 65), “nature” (claims 66-68), and “heparin-like glycosaminoglycan” (claim 70). Because the introduction of “exact chemical structure” (claim 63), “molecular weight” (claim 65), “nature” (claims 66-68), and “heparin-like glycosaminoglycan” (claim 70) lacks written support, these phrases are considered NEW MATTER.

This rejection is necessitated by amendment.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 36 and 37 is maintained and newly applied to new claims 54-72 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

This rejection is maintained (claims 36-37), necessitated by amendment (new claims 54-72), and reiterated for reasons of record.

Claim 36 (lines 2, 5, 8, 15, and 16) recites the phrase “*complete* building blocks” which is vague and indefinite. It is unclear what is considered to be a complete building block as opposed to an incomplete building block. For example, on page 6, lines 19-24, of the specification states a polysaccharide can include a monomeric building block or a dimeric building block. As such, it is unclear if applicants consider both or only one of these types of building blocks to be complete for a polysaccharide. This same issue of what is considered a complete building block also applies to the “complete building blocks of the query sequence” (claim 36, lines 5 and 15) which can be composed of a variety of polymers. Claim 37 and 54-72 are also rejected due to their direct or indirect dependency from claim 36.

Applicants submit that the specification provides adequate description of complete building blocks, such as on page 25, lines 1-6. This is found unpersuasive as the passage



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referred to by Applicants does not decisively define “complete building block”. Line 3 of the passage recites the word “including” and line 4 recites the term “etc.” which do not allow one skilled in the art to understand the metes and bounds of the phrase “complete building block”. Applicants mention differences between a “complete building block” and a “basic building block”; however, an “incomplete building block” is not necessarily a “basic building block”.

***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 36 and 37 is maintained and newly applied to new claims 54-55, 57, 61-62, and 69 under 35 U.S.C. 102(b) as being anticipated by Claverie et al. (Computers Chem., Vol. 17, No. 2, pp. 191-201).

This rejection is maintained and reiterated for reasons of record (claims 36 and 37) and necessitated by amendment (claims 54-55, 57, 61-62, and 69).

Webster’s NewWorld Medical Dictionary defines deoxyribonucleic acid (DNA) to contain deoxyribose which is defined to be a sugar component (monosaccharide). As the exact definition of polysaccharide is not specified in the instant specification, DNA can reasonably be interpreted to be a “polysaccharide” as it contains multiple monosaccharides. Due to the unclarity of “*complete* building blocks” (lines 1 and 2), these blocks are reasonably interpreted to

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be any type of material found in the query or “polysaccharide”. In this manner, these building blocks are reasonably interpreted to include the nucleotides of a DNA molecule.

Claverie et al. disclose a method of using algorithms on computers (reasonably interpreted to be a computer-readable medium) to make comparisons between query sequences and database sequences (abstract and page 191, col. 1, second paragraph). Claverie et al. disclose database comparisons include genes and cDNA (page 191, col. 2, first paragraph). In figure 3B, Claverie et al. disclose a query sequence in a data structure containing values represented by n’s (masked region) as well as As, Ts, Gs, and Cs representing unmasked regions. Figure 3A contains “EST1591 (210 nucleotides) human brain” wherein EST1591 is reasonably interpreted to be an identifier, while “(210 nucleotides)” and “human brain” are reasonably interpreted to be other fields giving information. Figure 3B lists sequence matches to the query which also contain names (identifiers) as well as other fields including numerical values. The mask in Figure 3B is directed toward Alu elements which are stored in the form of “n”s in the field representing the sequence (Figure 3B, lines 3-5). “Binary operation” is not succinctly defined in the instant specification. As Webster’s II New Riverside Dictionary defines “binary” to be composed of two different parts, Figure 3B lists the results of two different results based on operations performed during the sequence comparison. In particular these two operations performed include the score (third field from left) and the probability (fourth field from left) with values resulting from the masking procedure. The sequences listed in Figure 3B represent sequences that match between the query sequence and other sequences.

“Non-character based field” is not specifically defined in the instant specification, but the specification gives examples of values as either a binary or decimal value. Therefore, Claverie et

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al. list values in the fields of Figures 3A and 3B (rightmost field of each) which represent decimal values or non-character based fields, as stated in instant claims 54 and 57. The EST1591 identifier, as listed in Figures 3A and B, represent a numerical identifier, as stated in instant claim 55. The probability values as seen in Figures 3A and 3B represent properties of the sequences, as stated in instant claim 61. The EST1591 human brain information in Figure 3A represent the identity of the complete building block of the polysaccharide, as stated in instant claim 62. The sequence match results of Figures 3A and 3B represent a determination of properties matching between the query sequence and polysaccharide sequence with at least one non-zero result value, as stated in instant claim 69.

Thus, Claverie et al. anticipate claims 36-37 and 54-55, 57, 61-62, and 69.

Applicants state DNA and polysaccharides are treated separately in the instant specification and also in the related art. This statement is found unpersuasive as these terms were not specifically defined in the specification, each term is given is broadest reasonable interpretation. Applicants various passages within the specification as examples of how DNA and polysaccharides are treated as separate classes of polymers. This separate class treatment is found unpersuasive for page 2, lines 21-24, as the paragraph recites the term “may” in each description but does not state a decisive word such as “is”. The term “may” merely leads one of skill in the art to assume that these descriptions are just one of many possible interpretations of the subject material. This separate class treatment is found unpersuasive for page 5, lines 16-18. Here, the term “polysaccharide” is defined as a biopolymer comprised of linked saccharide or sugar units. DNA contains sugar units which are linked, so that it clearly fits the above-

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mentioned definition of “polysaccharide”. This separate class treatment is found unpersuasive for page 7, line 30 through page 8, line 5. While this passage does state various polymers, such as polysaccharides, nucleic acids, and polypeptides, there does not appear to be any statement that a nucleic acid cannot be a polysaccharide. Without such a definition, it is the duty of the Examiner to interpret each phrase or term in its broadest reasonable interpretation unless a definition is clearly stated for that phrase or term in the specification. Applicants submit Claverie et al. do not teach performing at least one binary operation and do not agree with the Examiner’s interpretation of the phrase “a binary operation”. Once again, due to the lack of a clear definition of this phrase, a broad and reasonable interpretation has been given to it during the comparison of this invention with potential prior art. This broad and reasonable interpretation of “a binary operation” is contained within the Claverie et al. reference. Therefore, this 35 USC 102(b) rejection is maintained.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

April 26, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER 4/29/04